

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 20

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte BARRY FARRIS

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Appeal No. 2004-1945  
Application No. 09/524,213

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ON BRIEF

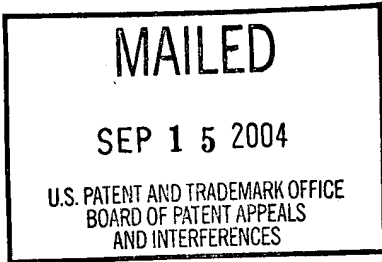
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Before COHEN, ABRAMS, and NASE, Administrative Patent Judges.  
NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 24 to 38 and 41 to 48. Claims 1 to 23, 39 and 40 have been withdrawn from consideration. No claim has been canceled.

We AFFIRM-IN-PART.



### BACKGROUND

The appellant's invention relates generally to a method and apparatus for storing a dry substance, activating the substance with liquid and subsequently transferring the substance from storage into a syringe or cannula without the need for a needle. More particularly, the appellant's invention relates to a storage container for storing a substance that has undergone a lyophilization process and is ready for the introduction of a liquid to dissolve the lyophilisate into a medium that may be then utilized according to its appropriate prescription (specification, p. 2). A copy of the claims under appeal is set forth in the appendix to the appellant's brief.

Claims 24 to 38 and 41 to 48 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,716,346<sup>1</sup> to Farris.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejection, we make reference to the final rejection (Paper No. 13, mailed March 17, 2003) and the answer (Paper No. 17, mailed January 8, 2004) for the examiner's complete reasoning in support of the rejection, and to the brief (Paper No. 16, filed November 24, 2003) for the appellant's arguments thereagainst.

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<sup>1</sup> Issued February 10, 1998.

### OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art reference to Farris, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

Initially we note that anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or the recognition of inherent properties that may be possessed by the prior art reference. See Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). A prior art reference anticipates the subject matter of a claim when the reference discloses every feature of the claimed invention, either explicitly or inherently (see Hazani v. Int'l Trade Comm'n, 126 F.3d 1473, 1477, 44 USPQ2d 1358, 1361 (Fed. Cir. 1997) and RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984)); however, the law of anticipation does not require that the reference teach what the appellants are claiming, but only that the claims on appeal "read on" something disclosed in the reference (see Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984)).

### **The teachings of Farris**

The primary object of Farris' invention was to provide a method and apparatus for transferring sterile fluid from an ampule to a hypodermic syringe without the need of a hypodermic needle. Farris discloses a needleless dosage transfer system for filling medicating devices such as syringes or needleless cannulas to minimize the likelihood of an unwanted needle stick and to avoid the initial cost of a needle as well as the disposal cost of the needle. As shown in Figures 1-6, Farris' needleless dosage transfer system includes a vial or ampule 10 formed from two parts: a body portion 20 and a cap portion 40. The body portion 20 is formed with flexibly deformable walls and defines a blind bore. An opening of the vial includes a tapered section 8 adapted to frictionally fit over a taper of a male luer-type fitting commonly found on syringes and needleless cannulas. By deforming the walls of the vial, fluid is forced from the vial into a syringe or needleless cannula. The opening of the vial is protected by the cap portion 40 and includes a scoreline which, when fractured, defines the opening. The cap portion which is to be removed from the vial prior to its use is fabricated as one piece with the body portion in order to assure sterile conditions during manufacture and filling. A tab 42 is associated with the cap portion which lists the ingredients within the vial. The body portion also supports an area which lists the vial's contents.

### Appellant's argument

Appellant argues (brief, pp. 11-13) that the following limitations (in bold) of independent claims 24, 31 and 48 are not disclosed by Farris and accordingly claims 24, 31 and 48 are not anticipated by Farris.

24. A needleless dosage transfer system, for removing a sterile pharmaceutical grade **nonliquid** from a sealed ampule to a needleless syringe or needleless cannula, comprising in combination,  
an ampule defined by an end and collapsible side walls extending from said end thereby defining a blind bore and an open end,  
said side walls formed from resilient, collapsible material,  
a coupler at said open end of said vial, and a removable cap occluding said open end,  
said coupler configured and provided with means to connect to an opening of the syringe or cannula in fluid communication therewith, whereby **the nonliquid** can be transferred from the ampule without an interconnecting needle after removing said cap, liquifying **the nonliquid** and coupling said opening to the needleless syringe or cannula.

31. An ampule for storing a **nonliquid** pharmaceutical product in a manner to **inhibit lability** of the product and permitting the transfer of the product in an aseptic manner to avoid nosocomial infection from ambient air comprising:  
resilient walls that can be collapsed and creating an orifice to pass a pharmaceutical **grade nonliquid fluid or solid** therethrough;  
an opening on said ampule whereby the opening is circumscribed by a coupler which is to be complementally fastened to receive a dose administering device.

48. A needless dosage transfer system, comprising, in combination:  
an ampoule having a **lyophilized pharmaceutical** aseptically located therewith; the pharmaceutical **characterized as being nonliquid**;  
an integrally formed cap closing said ampoule, said cap located at a score line on said ampoule to facilitate removal, said score line on said ampoule, once exposed by removal of said cap, dimensioned to receive a luer coupling thereat, and  
walls of said ampoule formed of deformable flexible non-porous material.

Appellant argues (brief, p. 13) that (1) claim 34 requires the nonliquid pharmaceutical be introduced from an open end opposite from the outlet, after which the open end is sealed; and (2) Farris does not disclose this limitation and accordingly claim 34 is not anticipated by Farris.

Appellant argues (brief, p. 13) that claims 41 to 47 are not anticipated by Farris since Farris' system does not include a filtered needle.

#### **Our decision**

##### *Claim 48*

We will not sustain the rejection of claim 48 under 35 U.S.C. § 102(b). Claim 48 recites "an ampoule having a lyophilized pharmaceutical aseptically located therewith; the pharmaceutical characterized as being nonliquid." Clearly, Farris' vial is not disclosed as having a lyophilized pharmaceutical aseptically located therewith; the pharmaceutical characterized as being nonliquid. As such, all the limitations of claim 48 are not disclosed by Farris.

##### *Claims 24 and 31*

We sustain the rejection of claims 24 and 31 under 35 U.S.C. § 102(b).

It is well settled that if a prior art device inherently possesses the capability of functioning in the manner claimed, anticipation exists whether there was a recognition that it could be used to perform the claimed function. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). See also LaBounty Mfg. v. Int'l Trade Comm'n, 958 F.2d 1066, 1075, 22 USPQ2d 1025, 1032 (Fed. Cir. 1992) (in quoting with approval from Dwight & Lloyd Sintering Co. v. Greenawalt, 27 F.2d 823, 828 (2d Cir. 1928)):

The use for which the [anticipatory] apparatus was intended is irrelevant, if it could be employed without change for the purposes of the patent; the statute authorizes the patenting of machines, not of their uses. So far as we can see, the disclosed apparatus could be used for "sintering" without any change whatever, except to reverse the fans, a matter of operation.

Moreover, the manner or method in which a machine is to be utilized is not germane to the issue of patentability of the machine itself. In re Casey, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967). A statement of intended use does not qualify or distinguish the structural apparatus claimed over the reference. In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). There is an extensive body of precedent on the question of whether a statement in a claim of purpose or intended use constitutes a limitation for purposes of patentability. See generally Kropa v. Robie, 187 F.2d 150, 155-59, 88 USPQ 478, 483-87 (CCPA 1951) and the authority cited therein, and cases compiled in 2 Chisum, Patents § 8.06[1][d] (1991).

In our view, the argued limitations of claims 24 and 31 (reproduced in bold above) are statements of intended use and do not qualify or distinguish the apparatus claimed over the apparatus disclosed by Farris. Clearly, the vial disclosed by Farris is fully capable of being used to store a dry substance, to later activate the substance with a liquid and then to transfer the substance from the vial into a syringe or cannula without the need for a needle.

Since the subject matter of claims 24 and 31 is met by Farris for the reasons set forth above, the decision of the examiner to reject claims 24 and 31 under 35 U.S.C. § 102(b) is affirmed.

*Claims 25 to 30, 32, 33 and 35 to 38*

Claims 25 to 30, 32, 33 and 35 to 38 which depend from claim 24 or claim 31 have not been separately argued by appellant. Accordingly, we have determined that these claims must be treated as falling with their respective independent claim. See In re Nielson, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987). Thus, it follows that the decision of the examiner to reject claims 25 to 30, 32, 33 and 35 to 38 under 35 U.S.C. § 102(b) is also affirmed.



*Claim 34*

We will not sustain the rejection of claim 34 under 35 U.S.C. § 102(b). Claim 34 requires the nonliquid pharmaceutical be introduced from an open end opposite from the outlet, after which the open end is sealed. Clearly, Farris' vial does not disclose this limitation.<sup>2</sup> As such, all the limitations of claim 34 are not disclosed by Farris.

*Claims 41 to 47*

We will not sustain the rejection of claims 41 to 47 under 35 U.S.C. § 102(b). Claims 41 to 47 recite that the system includes a filtered needle. Clearly, Farris' vial is not disclosed as being used in a system with a filtered needle. As such, all the limitations of claims 41 to 47 are not disclosed by Farris.<sup>3</sup>

CONCLUSION

To summarize, the decision of the examiner to reject claims 24 to 33 and 35 to 38 under 35 U.S.C. § 102(b) is affirmed and the decision of the examiner to reject claims 34 and 41 to 48 under 35 U.S.C. § 102(b) is reversed.

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<sup>2</sup> The examiner did not respond to the appellant's argument concerning claim 34.

<sup>3</sup> While Farris does disclose that a filtered needle has been used in prior systems (see column 1, lines 35-45), Farris does not teach that a filtered needle is used with his vial 10.

No time period for taking any subsequent action in connection with this appeal  
may be extended under 37 CFR § 1.136(a).


AFFIRMED-IN-PART



IRWIN CHARLES COHEN  
Administrative Patent Judge



NEAL E. ABRAMS  
Administrative Patent Judge



JEFFREY V. NASE  
Administrative Patent Judge

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# ROUTING FOR DECISIONS OF BOARD OF APPEALS

	Initials	Date
Director's Secretary	<u>R.T.</u>	<u>11-29-04</u>
Director	<u>RAB</u>	<u>11-29-04</u>
SPE	_____	_____
Examiner	_____	_____
Disposal Recorded by Applicant Examiner		_____

Date of Decision	Serial Number	Examiner	Art Unit	Assigned <input checked="" type="checkbox"/> Reversed
<u>9-15-04</u>	<u>04524213</u>	<u>Maur</u>	<u>3751</u>	

Comments